COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 10-VIII-2006
C(2006) 3722

NOT FOR PUBLICATION

COMMISSION DECISION

of 10-VIII-2006

concerning the implementation of conditions or restrictions set out in Article 127a of Directive 2001/83/EC of the European Parliament and of the Council concerning a marketing authorisation for "Thelin - Sitaxentan sodium", an orphan medicinal product for human use

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(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EEC) No 2309/93 of 22 July 1993 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products[1],

Having regard to Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency[2], and in particular Article 9(4)(c) thereof,

Having regard to Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use[3], and in particular Articles 33, 34 and 127 (a) thereof,

Having regard to the application submitted by Encysive (UK) Limited on 17 August 2005 under Article 4(1) of Regulation (EEC) No 2309/93 and to the favourable opinion of the European Medicines Agency, formulated by the Committee for Medicinal Products for Human Use on 1 June 2006,

Whereas:

(1) "Thelin - Sitaxentan sodium" complies with the requirements set out in Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use[4].

(2) It is therefore appropriate to authorise its placing on the market. To this effect, Commission Decision C(2006) 3721 of 10-VIII-2006 granting marketing

[1] OJ L 214, 24.8.1993, p. 1. Regulation as last amended by Regulation (EC) No 1647/2003 (OJ L 245, 29.9.2003, p. 19).
[2] OJ L 136, 30.4.2004, p. 1
[3] OJ L 311, 28.11.2001, p. 67. Directive as last amended by Directive 2004/27/EC (OJ L 136, 30.4.2004, p. 34).
[4] OJ L 311, 28.11.2001, p. 67. Directive as last amended by Directive 2004/27/EC (OJ L 136, 30.4.2004, p. 34).

authorisation to the orphan medicinal product "Thelin - Sitaxentan sodium" is simultaneously being addressed to Encysive (UK) Limited.

(3) The marketing authorisation is subject to conditions or restrictions with regard to the safe and effective use of the medicinal product. It is appropriate that implementation of these conditions is ensured by the Member States.

(4) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on Medicinal Products for Human Use,

HAS ADOPTED THIS DECISION:

Article 1

The Member States shall ensure implementation of the conditions or restrictions with regard to the safe and effective use of the orphan medicinal product set out in Annex.

Article 2

This Decision is addressed to the Member States.

Done at Brussels, 10-VIII-2006

For the Commission
Heinz ZOUREK
Director-General